FDA 510(k) Premarket Notification

K253486 SKIA-Head (Model: SKIA-ST00)

CLEARED

Feb 23, 2026
129 days to decision

K253486 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k253486/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 17, 2025
Decision date	Feb 23, 2026
Days to decision	129 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Skia, Inc.**
Location	Seoul, KR
Contact	Jong Myoung Lee
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov